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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/782,056 | 02/18/2004 | Rob Worsham | 12013/50101 | 5746 |
| 23838 | 7590 | 12/21/2005 | EXAMINER | |
| KENYON & KENYON 1500 K STREET NW SUITE 700 WASHINGTON, DC 20005 | | | MICHENER, JENNIFER KOLB | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1762 | |

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/782,056

Applicant(s)

WORSHAM, ROB

Examiner

Jennifer K. Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9 and 31-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/26/05; 7/13/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Based on claim Amendments, the following rejection has been amended:

2. Claims 1, 3-9 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu (NPL document cited by Applicant) in view of Buscemi et al. (5,968,092).

Wu teaches a method of coating a device by vaporizing a frozen target with a laser beam to deposit a bio-layer on the device (abstract).

Wu's frozen target may be a therapeutic agent or polyethylene glycol (PEG), or composites, in a solution within a solvent (Introduction, Sections 2.2, 3.1, and 4.1).

Wu teaches an exemplary method of coating a bio-sensor, but Wu teaches that his materials and techniques are directly applicable to areas such as biocompatible coatings for medical implants and implantable devices (p. 608, col. 1, lines 3-5). It is Examiner's position that the term medical implantable devices is inclusive of stents.

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Additionally, Examiner cites Buscemi. Buscemi teaches that stents are desirably coated with a composite coating mixture of polyethylene glycol and therapeutic agents (col. 8, lines 34-45).

Since Wu teaches coating implantable medical devices with PEG and therapeutic agents using a frozen target and an energy beam and Buscemi teaches coating stents, which are implantable medical devices, with PEG and therapeutic agents, Buscemi would have reasonably suggested the use of a stent substrate in the method of Wu. It would have been obvious to one of ordinary skill in the art to use the teachings of Buscemi in the method of Wu to provide Wu with a suitable example of an implantable medical device on which the coating of his invention could be deposited using the method of his invention.

Regarding the newly-added limitations requiring providing a stent holder for moving a first stent into and out of the coating chamber and moving a second stent into and out of the chamber, etc., Examiner notes that Wu teaches that the "substrate is placed directly in front of the target" (p. 609, col. 2, line 14). Such placement would inherently require a holder that moves the stent into the chamber. When coating is complete, the stent is inherently moved out of the chamber, as well. Wu does not specifically teach coating a subsequent stent in the same manner, however, Wu does teach that "Implants may require coatings" in the plural. It is Examiner's position that it would have been obvious to coat more than one stent using the method of Wu since Wu teaches that a plurality of stents will require such coating. It is well-known in the manufacturing art to create a plurality of objects for mass-production and sale. Manufacturing processes are typically

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either done in batch processes or in continuous fashion. It would have been obvious to one of ordinary skill in the art to select either a batch or continuous coating process.

Since Wu teaches only the option of coating his one stent, alone, it is Examiner's position that it would have been obvious to the ordinary artisan to have selected a continuous process of coating stents individually, as is done by Wu, one after the other, as required by the claims. In general, the repetition of a process step does not patentably distinguish the process.

Wu's frozen target is mounted on a refrigerated assembly. The assembly may be rotated (Fig. 2(a)) within a vacuum chamber, subjecting the target to a pulsed laser beam, after which the solvent is pumped away for deposition of the target.

Wu teaches creation of multilayer composite structures using the pulsed laser deposition method of his invention (Conclusion), inherently requiring directing the laser beam at another frozen target.

Regarding claim 7, it appears from Figure 2a that the vaporized target material is directed towards the substrate, however Wu does not specifically teach transporting the material within a directed "gas flow". However, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to enhance the flow of the target coating by directing it to the desired substrate using a suspending gas stream.

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Regarding claims 31-33, Wu's vapor inherently forms a coating on the portion of the device. An implantable device is three-dimensional and therefore some end thereof will be coated and some portion that is facing away from the target matrix will not be coated (see Figure 2a). Wu also teaches patterning which leaves some portions uncoated (p. 609, col. 1). Wu teaches that composites, patterns of biomaterials (plural), and multi-layer coatings can be placed on the substrate using this method or in combination with other printing techniques (p. 613, col. 2). While it is not explicitly stated, it is Examiner's position that the use of different materials in different coating steps using different techniques will inherently apply some materials in some portion of the substrate and other materials in other portions of the substrate.

The submission of the IDS of 7/26/05 prompted this new ground of rejection:

3. Claims 1, 3-9 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talton (WO 03/061840).

Talton teaches a method of coating substrates, plural, such as stents, with continuous or discontinuous coatings of polymer and therapeutic agent, using a pulsed laser (p. 2, 3, 4, 6, 7). Examples teach moving the substrate into the chamber and removing the substrate when coating is complete. Talton teaches that the target material may be frozen and a chiller supplies cold air to the portion of the container holding the target, qualifying as refrigerated (p. 12). Talton teaches directing an energy beam (laser) at the frozen target, vaporizing a portion of the target, and contacting the stent with the vapor to coat the stent with the polymer and therapeutic agent (throughout).

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Regarding the newly-added limitations requiring providing a stent holder for moving a first stent into and out of the coating chamber and moving a second stent into and out of the chamber, etc. to provide for a continuous process, Examiner notes that Talton teaches that his atmospheric pressure method allows for a continuous production process where uncoated substrates are transported into a coating chamber and coated (p. 9). Such placement/transport would inherently require a holder that moves the stent into the chamber. When coating is complete, the stent is inherently moved out of the chamber, as well, as taught by the Examples. Talton teaches coating individual substrates (Examples) in a continuous fashion (p. 9), which would require moving stents into the chamber and out of the chamber in succession, as required by Applicant. Additionally, it is well-known in the manufacturing art to create a plurality of objects for mass-production and sale.

The matrix target of polymer and therapeutic agent may be dispersed in a solvent (p. 11).

The matrix target assembly may rotate (p. 12, p. 13).

The chamber removes excess gas, which would include solvent, via exhaust duct (p. 12, throughout).

Talton teaches gas flow to transport the vapor to the stents (p. 13 and throughout).

As taught above, the energy beam may be pulsed.

As taught above, Talton teaches discontinuous coatings. Additionally, he teaches the application of various agents to the substrates in quick succession, enabled by his ambient pressure process, which would require another frozen target.

Response to Arguments

4. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

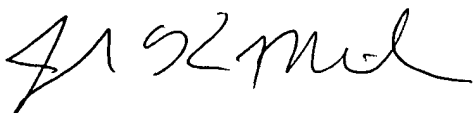
6. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 7/26/2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Mondays & on Tuesday and Wednesday afternoons.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Michener
Patent Examiner
Art Unit 1762
December 18, 2005